IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION **Master File No. 2:12-md-2327**

THIS DOCUMENT RELATES TO: **MDL No. 2327**
WAVE 1 CASES

PLAINTIFFS' RESPONSE TO DEFENDANTS' MOTION TO EXCLUDE THE TESTIMONY AND OPINIONS OF DR. JIMMY W. MAYS, PH.D.

Plaintiffs respond to Defendant Ethicon, Inc. and Johnson & Johnson's (collectively, "Ethicon"), Motion to Exclude Plaintiffs' expert, Jimmy W. Mays, Ph.D., as follows:

INTRODUCTION

Ethicon's Motion retreads old ground and confuses the issues before the Court. This Court has previously held that Dr. Mays's opinions regarding degradation of polypropylene and the mechanism of oxidative degradation of polypropylene is admissible. *See generally, Frankum v. Bos. Sci Corp.*, No. 2:12-cv-00904, 2015 WL 1976952 (S.D.W. Va. May 1, 2015), *Eghnayem v. Bos. Sci Corp.*, 57 F. Supp. 3d 658 (S.D.W. Va. 2014); *Sanchez v. Bos. Sci Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D.W. Va. Sept. 29, 2014). Dr. Mays is a Polymer Scientist with 30 years of experience in synthetic polymers. Ex. A, Expert Report of Jimmy W. Mays (January 12, 2016) ("Mays Report"). He is a Professor of polymer chemistry at The University of Tennessee with a co-appointment at the Oak Ridge National Laboratory. *Id.* at 1. Prior to starting his career as a professor, Dr. Mays spent five years working in the Central R&D of Hercules Inc. *Id.* at 1-2. At the time, Hercules was one of the world's largest producers of polypropylene, and Dr. Mays was the technical liaison between central R&D and Hercules Fibers Technical Center, which is where polypropylene fibers were produced on a massive scale,

see id.; the Ethicon mesh products at issue in this case are all made from polypropylene fibers. The opinions expressed by him are based on his experience, good science and measurable data (including information collected by Ethicon) that describe what has been known regarding polypropylene's reactivity since the time of the polymer's discovery. Dr. Mays intends to offer expert opinions based upon the current state of knowledge within the scientific community on polypropylene.

Ethicon claims that the antioxidant package in the Prolene polypropylene blend makes it unique from other polypropylene, and argues that since the available peer-reviewed literature does not specifically state that Prolene degrades, that Dr. Mays needs to test it—and find degradation—before he can opine at trial. This argument, however, ignores the actual findings in the literature, as well as the evidentiary standards set by Federal Rule 702 and *Daubert. See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587 (1993). Dr. Mays's report explains the mechanism for polypropylene's—including Prolene's—degradation. His opinions are supported by his experience and education, the scientific literature, and Ethicon's own documents—which show that Prolene degradation takes place *in vivo.*

Additionally, the underlying question of the admissibility of the testimony Ethicon is trying to exclude has been previously ruled on by this Court in the *Lewis* and *Cisson* cases.[1] There, experts with qualifications similar to those of Dr. Mays were permitted to offer general

[1] The Court held: "First, Ethicon ignores Dr. Klinge's statements that clearly ascribe particular complications to degradation, fraying, and particle loss. For instance, he states that 'such oxidation and degradation, depending upon the severity, can [create] an enhanced inflammatory tissue response due to increased surface area as well as the lack of a smooth surface coming into contact with the tissue.' (Klinge Report [Lewis Docket 132-2], at 37). Second, Dr. Klinge's opinions are based, at least in part, on peer-reviewed, published literature. (See Klinge Report [Docket 132-2], at 33 (citing studies by Williams et al., Liebert et al., and Oswald et al.)). I therefore FIND that Dr. Klinge is permitted to testify generally about polypropylene's tendency to degrade, fray, or lose particles and its effect on the human body."; *see also* (*Cisson v. C.R. Bard, Inc.*, C.A. No. 2:11-cv-00195, Dkt. No. 274, pp. 36-37; *Cisson*, Dkt. No. 280, pp. 6-7 (holding upon motion for reconsideration that Dr. Klosterhalfen could testify about the degradation of polypropylene and the effects of polypropylene degradation generally)).

causation opinions in regards to polypropylene degradation based on: (1) the scientific literature, (2) their experience, and (3) their review of internal Ethicon documents.

Ethicon also argues that Dr. Mays should not be allowed to opine about the clinical complications caused by degradation and Ethicon's state of mind or corporate conduct. Plaintiffs will address why each of these arguments also fail.

STANDARD OF LAW

Under Rule 702 of the Federal Rules of Evidence, as interpreted by the Supreme Court in *Daubert*, an expert witness may be qualified by "knowledge, skill, experience, training or education." Fed. R. Evid. 702. The witness's testimony also must represent "scientific knowledge," meaning that it is supported by appropriate validation; and it must assist the jury, meaning that it must be relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995).

The court's focus in a *Daubert* inquiry should be solely on experts' "principles and methodology, not on the conclusions that they generate." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Notably, "the Supreme Court itself viewed *Daubert* as a *liberalization*, not a tightening, of the rules controlling admission of expert testimony." *Cavallo v. Star Enterprise*, 100 F.3d 1150, 1158 (4th Cir. 1996) (emphasis added). Further, "exclusion is the least favored means of rendering questionable scientific evidence ineffective." *Id.*

The *Daubert* Court listed several factors to guide trial courts in their determinations. They include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir.

2003), *quoting Daubert*, 509 U.S. at 593–94. However, "[t]he inquiry to be undertaken by the district court is a flexible one." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999); *see also Daubert*, 509 U.S. at 594–95; *Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that Daubert's five factors neither necessarily nor exclusively apply to every expert"). In the end, an expert's testimony is admissible if it "rests on a reliable foundation and is relevant." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999).

ARGUMENT

I. DR. MAYS'S OPINIONS ARE RELEVANT AND RELIABLE, AND ETHICON'S POSITION ON THE NEED FOR TESTING PROLENE IS FUNDAMENTALLY FLAWED.

Ethicon has attacked Dr. Mays's opinion by arguing that they are based on conclusions drawn for generic polypropylene, and therefore, are completely unreliable when considering Ethicon's Prolene polypropylene blend. This argument is nonsense. Prolene is 99.8 percent polypropylene. Ex. B, Mays 3/2/2016 Dep. Tr. 34:6:11 ("Mays Dep."). By claiming that Dr. Mays's degradation opinions (which relate to ALL polypropylene blends) do not apply to Ethicon's Prolene products, specifically, Ethicon is ignoring what is known about polypropylene generally and are making arguments that have absolutely no bearing on this case and no basis in science. In no way can the assumptions embedded into Ethicon's argument that Prolene is special and unique be taken at face value. The peer-reviewed literature, the scientific data collected by Ethicon, and Ethicon's own documents produced in this litigation (including the Material Safety Data Sheet ("MSDS") for its Prolene resin), all support the application of Dr. Mays's opinions to Prolene and all the Prolene mesh devices at issue. Ethicon's insistence on the need for testing Prolene, and their attacks regarding the lack of merit in Dr. Mays's report,

cannot withstand scrutiny. Dr. Mays is qualified to proffer his scientifically reliable general causation opinions to a jury in this case.

a. Ethicon's insistence that Dr. Mays needed to perform testing on Prolene is entirely misplaced.

Throughout their brief, Ethicon argues that Dr. Mays's opinions on degradation are not reliable and therefore should be excluded because his opinions relate to polypropylene, not Prolene, and he has not performed any tests on Prolene. *See generally* Def. Brf. Ethicon asserts that it is inconsistent with the "intellectual rigor" employed by a polymer chemist to make conclusions about the specific characteristics of a specific substance in the absence of testing. *Id.* at 4. The law does not require "testing" of any kind, including the testing of specific physical evidence that Ethicon claims is required here. *Kingsley v. Brenda and Gene Lummus, Inc.*, No. 1:11cv32, 2012 WL 727091, *7 (W.D.N.C. Mar. 6, 2012) ("*Daubert*, however, 'does not require an expert to perform testing before his opinion is admissible."); *see also Blevins v. New Holland N. Am., Inc.*, 128 F. Supp. 2d 952, 957 (W.D. Va. 2001) (rejecting argument that expert opinion was inadmissible due to lack of testing where expert had relevant professional experience and had written about the issue under the auspices of a recognized professional organization).

While Dr. Mays agrees that performing tests on explanted mesh can be an important piece of evidence, it is simply not necessary for him to formulate his opinions.

> Q. And Doctor, can you make any type of prediction about whether or not the mesh from these 28 plaintiffs will oxidize?
> A. Yes, I can.
>
> Q. And what do you base that on?
> A. My experience with polypropylene, my characterization of polypropylene-based meshes. …The literature that Ethicon has in-house going back to the early 80s where they again and again see evidence of oxidative degradation of polypropylene implants. Ex. B, Mays Dep. 43:20-44:7.

The only testing that is required here is the testing of the expert's theory underlying his opinion, not the physical evidence at issue. When courts discuss the "ability to test" under *Daubert*, they are not requiring physical testing or examination of the product at issue—such as the explanted mesh in this case—but the ability to test the underlying basis of the expert's opinions. *Daubert*, 509 U.S. at 593 ("A key question to be answered in determining whether a ***theory or technique*** is scientific knowledge that will assist the trier of fact will be whether it can be (and has been) tested").

Simply put, Dr. Mays opines on the basic characteristics of polypropylene as they are known and accepted in the scientific community as he has been allowed to do several times before in this litigation. Furthermore, his qualification as an expert has never been contingent upon him testing the specific polypropylene at issue. What makes Ethicon's arguments here most nonsensical is that Dr. Mays relies upon Ethicon's own tests of Prolene polypropylene that concluded that Prolene polypropylene does in fact degrade.

b. Ethicon's reliance on selected case law is equally misplaced.

No case cited by Ethicon contains any language or holding that requires physical testing of the evidence at issue. In *Marsh v. W.R. Grace & Co.*, 80 Fed. Appx. 883, 886 (4th Cir. 2003), the court excluded the expert's opinion because the expert started from a conclusion and then generated, without testing, the hypotheses to support that conclusion. The Court goes on to say that his opinion is unreliable because it cannot be tested or verified consistently. *Id.* The Fourth Circuit also took issue with the *Marsh* expert because his conclusion had not been subject to peer review or publication and was in fact inapposite to much of the scientific literature on the subject. *Id.* at 887. The exact opposite is true in this case. Dr. Mays's degradation opinions can be and have been verified, and the specific mechanisms of polypropylene degradation have been

known for many decades and come from published, peer-reviewed, scientific literature. *See generally*, Ex. A, Mays Report. Ethicon's arguments, relying on *Marsh*, are entirely unconvincing and unfounded.

II. DR. MAYS PROPERLY RELIES ON SCIENTIFIC LITERATURE.

As explained in *Daubert*, "[s]cientific methodology… [is] based on generating hypotheses and testing them to see if they can be falsified; indeed, this methodology is what distinguishes science from other fields of human inquiry." *Daubert*, 509 U.S. at 593. Following the decision in *Daubert*, courts have made employing scientific methodology a benchmark for the admissibility of expert testimony under Fed. Rule 702; the strength of this decision, however, lies in how crucial scientific methodology is to scientific advancement. The advancement of science is why scientific journals, like the ones Dr. Mays relies upon for many of his opinions in this case, publish peer-reviewed articles following a general outline. They describe the hypothesis on which the experiment is based, the materials and methods used to test that hypothesis, the results of that testing, and there is also usually a discussion of the conclusions drawn by the researcher(s). By explaining the scientific methodology employed in a given study, the readership can compare one study to the next, use one study's findings as support for further research, and even reproduce the experiment to get similar results. The opinions Dr. Mays is offering in this litigation are all based on measurable data with repeatable results from countless scientific experiments, many of which are recounted in the literature he relies upon to express his opinions. When combined with his own education and experience, the opinions he offers are certainly reliable and material to this case.

Moreover, Ethicon's Motion ignores scientific methodology and presupposes that Ethicon's Prolene polypropylene products are distinct from all other forms of polypropylene.

Based upon that argument, they argue that Prolene is chemically distinct from generic polypropylene due to its antioxidant package. Def. Brf. at 4-6. Ethicon goes on to assert that because most of the literature regarding polypropylene cited by Dr. Mays does not address Prolene specifically, it cannot support his opinions. *Id.* Ethicon then asserts that even the literature that specifically addresses Prolene does not support his degradation opinions. *Id.* This is complete nonsense. As explained above, these arguments are not only unfounded in the law, but they are also explicitly contrary to the available scientific literature and are devoid of scientific merit.

Dr. Mays relied upon hundreds of peer-reviewed scientific articles to help formulate his expert opinions. The peer-reviewed articles that specifically reference Prolene are only a small piece of evidence that contribute to his overall opinion regarding oxidative degradation of polypropylene including Prolene. The fact that some of these studies do not assess Prolene in the female pelvic floor does not diminish their reliability or relevance to the issue at hand. Specifically, Dr. Mays uses these articles to bolster his opinion that polypropylene, which again includes Prolene, degrades inside the human body.

- **Jongebloed Article**: Prolene suture implanted in the human eye showed severe degradation of the surface layer. Ex. A, Mays Report at 15.
- **Costello Article**: Polypropylene hernia meshes (produced by C.R. Bard and Ethicon) is susceptible to oxidation due to its chemical structure and results in deterioration of its physical properties *in vivo. Id.* at 16.
- **Mary Article**: Prolene suture showed visible evidence of surface stress cracking after 1 and 2 years *in vivo. Id.*

All of the above mentioned articles have been published in peer-reviewed scientific journals and are reliable. Ethicon takes further issue with the Mary article and states that is has unreliable methodology. This is patently false.

A. FTIR Test in the Mary Article is Reliable.

First, it should be noted that the Mary article, *Comparison of the In Vivo Behavior of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery,* was published in a highly respected peer-reviewed journal, thus the methodology is presumed reliable. Ex. C, C. Mary, *et al., Comparison of the In Vivo Behavior of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery*, 44 Am. Soc'y Artificial Internal Organs J. 199 (1998) ("Mary Article"). Regardless, Ethicon argues that because the author failed to take into consideration that one of Prolene's antioxidants has the same wavelength as the carbonyl group that indicates oxidation, the methodology is unreliable. While, it is true that DLTDP also has a wavelength of 1740 on an FTIR, this does not make the study unreliable nor affect its results. As Dr. Mays explained:

> Q. Did they recognize that wavelength for DLTDP, is my question?
> A. They did not, but they cleaned the sample and that would remove surface antioxidants. Plus, the sutures had been in the body for two years, which would also deplete antioxidants present at the surface. Ex. B, Mays Dep. 124:8-13.

By the time the explants in the Mary article were tested, DLTDP was no longer present on the surface of the explant, and thus could not give a false positive for oxidation in the FTIR test. Ethicon's argument that the study failed to determine whether the peak at 1740 was a reading of the antioxidant is completely misplaced. The 1740 peak seen in the Mary article was and could only have been from the carbonyl group that formed because of oxidative degradation.

B. The Cleaning Protocol in the Mary Article is Reliable.

Ethicon also argues that the study is unreliable because it ignores the fact that the sutures were treated with either formalin or gluteraldehyde prior to cleaning. Def. Brf. at 9. Ethicon's only basis for this argument is the flawed "polymer" theory of Dr. Shelby Thames, one of Ethicon's paid experts. *Id.*

"In order to study the surface chemistry of explanted prostheses, it is necessary to remove all the tissue that may have grown over and within the prosthetic structure. In the event that an explant has been treated with a fixative agent after retrieval, such as formaldehyde or glutaraldehyde, the tissue will be cross-linked and the only effective way of completely removing it is to use hydrolytic chemicals." Ex. D, Z. Zhang, et al., *Chemical and morphological analysis of explanted polyurethane vascular prostheses: the challenge of removing fixed adhering tissue.* 17 Biomat. J. 19 (1996). Cleaning agents like bleach and the enzyme used in the Mary article, both hydrolytically degrade the adhering tissue, which removes it from the explanted polypropylene.

Additionally, there is an ASTM protocol for cleaning polypropylene.[2] Ex. B, Mays Dep. 131:12-18. This protocol requires the material to be cleaned with a bleach solution, and this is the same cleaning protocol that Ethicon's own scientist use. *See id.* at 131:19-22.

Ethicon argues that this method is insufficient to remove the fixed protein layer because it has crosslinked with formalin and become stronger. This argument has no basis in science. Formalin has been used for over 50 years to "fix" explanted material to prevent it from decaying so that it can be scientifically evaluated at a later time. The ASTM protocols were developed with full knowledge of this. This "new" crosslinked polymer that Dr. Thames references, is

[2] It should be noted that the ASTM cleaning protocol is for cleaning polyethylene. However, polypropylene is chemically most closely related to polyethylene, and since there is no specific ASTM protocol for cleaning polypropylene, it makes logical sense to apply the polyethylene protocol.

nothing more than him misnaming a well-known and well understood chemical reaction. *See* Ex. E, H. Fraenkel-Conrat, *et al., The Reaction of Formaldehyde with Proteins. V. Cross-linking between Amino and Primary Amide or Guanidyl Groups*. 70 J. Am. Chem. Soc 8 (1948) (This article described the cross-linking methylene bridge that forms.)

III. ETHICON IGNORES THEIR OWN DEGRADATION FINDINGS REGARDING PROLENE.

Ethicon's Motion ***ignores the conclusions of its own scientists*** regarding the oxidative degradation and embrittlement of its Prolene blend *in vivo*. As Dr. Mays's report points out, Ethicon's principle scientist, Dan Burkley, did a study in 1987 that concluded that Prolene degradation occurred on the surface of the Prolene fibers. Ex. A, Mays Report at 25. In 1992 Dr. Burkley authored a memo that concluded that degradation of Prolene was still increasing seven years post implant. *See id*. And even though this information has been known to Ethicon since the 1980's—including the SEM images from that study and others concluding that Prolene is showing progressively increasing surface degradation over time *in vivo*—Ethicon continues to argue against their own findings. **Ethicon's paid expert, Dr. Shelby Thames, explains this finding away arguing that Dr. Burkley was a "very young scientist" when he concluded that Prolene degraded *in vivo.*** *See* Ex. F, Excerpt of 3/24/2016 Thames Dep. Tr. at 137:13-21 ("Thames Dep.").

Moreover, even if Ethicon is willfully blind to the fact that their Prolene polypropylene blend is susceptible to oxidation, the manufacturer of the resin used to make Prolene has provided Ethicon with an MSDS explaining that *it is reactive to strong oxidizing agents*. Ex. A., Mays Report at 26.

A. Loss of Molecular Weight is Not a Fundamental Component of Oxidative Degradation.

Ethicon does not contest the fact that their internal studies found *in vivo* degradation. Instead, they argue that their own conclusions must be wrong because there was no change in molecular weight found and thus there could be no degradation. Def. Brf. at 10. This argument is also completely based upon a flawed theory of Dr. Thames. Dr. Thames testified that this mistake was also due to Dr. Burkley being a young and inexperienced. *See* Thames Dep. at 137:13-21.

Degradation is defined as the change of the chemical structure. Ex. B, Mays Dep. 78:6-7. It does not also mean the loss of molecular weight. *Id.* at 78:8-15. While degradation can certainly be loss of molecular weight, oxidative degradation can also result in an increase in the molecular weight of the material. *See id.* at 78:19-79:17. Ethicon's argument that loss of molecular weight is a fundamental component of oxidative degradation is fundamentally wrong.

B. FDA Evidence for Prolene Sutures is Irrelevant.

Ethicon argues that if Dr. Mays is allowed to testify that Prolene degrades based upon his review of internal documents, Ethicon must be allowed to introduce evidence regarding FDA approval of Prolene sutures. Def. Brf. at 11. First, Dr. Mays's degradation opinion is based upon his 30 years of experience as a Polymer scientist, his review of hundreds of peer-reviewed scientific literature, *and* internal Ethicon documents.

Second, this Court has consistently excluded FDA evidence under Federal Rules of Evidence 402 and 403. Specifically, this Court has ruled that FDA evidence poses a substantial risk of misleading the jury and confusing the issues. In fact, Ethicon itself has argued that evidence related to FDA regulation is misleading and irrelevant. Mem. Op. & Order, *Lewis v. Johnson & Johnson*, No. 2:12-cv-04301 (S.D. W. Va. January 15, 2014) [Docket 196], at 9-10.

Specifically, Ethicon argued that a jury may attach undue significance to an FDA determination. *Id.* That argument still holds true.

Ethicon now argues that they should be allowed to introduce evidence regarding Prolene sutures because (1) the FDA approved a label that stated Prolene sutures were "not subject to degradation or weakening by the action of tissue enzymes in 1988, and (2) the FDA's PMA review is much more rigorous than the 510(k) process.

As evidenced by Dr. Mays's report, in the early 1980s Ethicon's internal studies concluded that Prolene sutures did in fact degrade. Ex. A, Mays Report at 24-26. In 1981 surface cracks were measured in Prolene sutures. *Id.* In 1983 cracks were found in explanted Prolene sutures. *Id.* Ethicon even formed a "Microcrack Committee" to investigate the problem. *Id.* Ethicon failed to inform the FDA of all their findings, which resulted in a false representation on the label. Ethicon is not prejudiced by not being allowed to use this evidence. In fact, it would be highly prejudicial to Plaintiffs and misleading to the jury if they were in fact allowed to use this evidence. Additionally, it would require Plaintiffs to prove that Ethicon withheld this information from the FDA, which could lead to a "fraud on the FDA" cause of action that is preempted by *Buckman. Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001).

Ethicon argues that because the FDA's PMA review is more rigorous, any allegations of design defects in Prolene sutures would be preempted. Def. Brf. at 12. While this is true, it is completely irrelevant. Plaintiffs are not suing for design defect in Prolene sutures. Plaintiffs are suing for design defects in polypropylene mesh devices that are intended to be implanted in the female pelvic floor. Prolene suture degradation evidence is intended by Plaintiffs to establish notice of polypropylene degradation, not that Prolene sutures are defectively designed. Ethicon's argument to allow FDA evidence is misplaced and irrelevant.

IV. DR. MAYS IS QUALIFIED TO OPINE ON THE MECHANISM BY WHICH OXIDATIVE DEGRADATION CAUSES CLINICAL HARM.

Dr. Mays is an expert in polymer synthesis and polymer characterization. Ex. B, Mays Dep. 10:1-2. While he is not an expert in the female anatomy or a medical doctor, he is qualified to opine on "what happens to polypropylene [implants] when they undergo degradation, and the mechanical mismatch between the degraded implants and the soft tissue that surrounds it; that's the root cause of these problems." *Id.* at 53:13-20. "Oxidative degradation is at the core of what's happening to these materials inside the human body." *Id.* at 50:24-25:1. "Oxidative degradation is behind all of these removals." *Id.* at 51:24-52:1. Dr. Mays is more than qualified to offer these opinions based upon his 30 years of experience as a professor and polymer scientist.[3]

Additionally, Dr. Mays is qualified to opine on how degradation causes clinical harm.

> Q. And, Doctor, are you qualified to teach students at UT how degradation can cause clinical harm?
> A. Yes I am. I've taught a lot of biomedical students in the past.
>
> Q. And, Doctor, have you ever taught any students at UT that degradation causes clinical harm?
> A. Certainly I have done that, yes. *Id*. at 54:5-11.

Furthermore, Dr. Mays has educated his colleagues at UT medical school about the clinical harm degradation causes.

> Q. Doctor, have you ever told the doctors at UT that Prolene mesh should not be used to treat SUI or POP?
> A. I cautioned them about mesh broadly.
>
> Q. Okay. But my question is specifically about Prolene. Have you ever told the doctors at UT that Prolene mesh should not be used to treat SUI or POP?
> A. When I told them that polypropylene mesh should not be used, that it's a bad idea, that it's susceptible to degradation inside the human body, they should know that Prolene is polypropylene-based pelvic mesh, just like Marlex is. *Id.* at 58:3-15.

[3] For 14 years Dr. Mays taught a course on Polymeric Materials to Biomedical Engineers and Materials Engineers. See Ex. A Mays Report at 3.

Dr. Mays is qualified to opine on the mechanism by which oxidative degradation causes clinical harm inside the human body.

V. STATE OF MIND DR. MAYS IS NOT OFFERING OPINIONS REGADING CORPORATE STATE OF MIND.

As it has done with every one of Plaintiffs' experts, Ethicon attempts to limit Dr. Mays's testimony by mischaracterizing his opinions as "state of mind" testimony. Dr. Mays has no such opinions in his report, and he will not be offering opinions concerning Ethicon's state of mind or corporate misconduct at trial. Dr. Mays is very clear that he is offering the following opinions: (1) polypropylene is susceptible to oxidation degradation and it degrades by an oxidative mechanism in the body and 2) because of their susceptibility to oxidation, Ethicon's Prolene polypropylene mesh is not suitable for permanent implantation in the human body.

To support their argument, Ethicon points to several statements made by Dr. Mays in his report wherein he references certain internal corporate documents in support of his opinions regarding the unsuitability of Prolene polypropylene mesh for permanent implantation in the human body. This falls squarely within the parameters previously recognized by this Court – "an expert may testify as to a review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible…." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 610 (S.D.W.Va.2013).

In *Smith v. Pfizer*, 714 F.Supp.2d 845 (M.D.Tenn.2010), the Court denied a similar *Daubert* motion arguing that the plaintiff's expert had offered improper "state of mind/intent" opinions, stating as follows:

> [Plaintiff's expert] King may properly testify as to his interpretation of internal marketing-related documents that he relied on in forming his opinions. *See In re Seroquel Prods. Liab. Litig.*, No. 6:06–md–1769, 2009 WL 3806436, at *4 (M.D.Fla. July 20, 2009) (holding that expert witnesses may 'rely on and discuss [the defendant's] internal corporate documents.... To rule otherwise would unduly

> restrict Plaintiffs' experts from explaining the bases of their opinions.'). He may not, however, testify as to the defendants' motives or intent. *Id.* The defendants highlight instances of arguably objectionable portions of King's testimony in previous MDL cases. (*See* Docket No. 119 at 11, 11 n. 12.) But King's statement, which has been filed with the court and will constitute his direct testimony in this case, does not contain any speculation regarding the defendants' motives or intent. (*See* Docket No. 180, Ex. 6.) The court notes that the defendants may object at trial if they believe that King's testimony, outside of his statement, improperly discusses motive or intent.").

Here, neither Dr. Mays's report nor his testimony contain any speculation regarding Ethicon's motives or intent. Ethicon's internal documents that he reviewed contain conclusions by Ethicon scientists from the early 1980s that Prolene polypropylene undergoes oxidative degradation. Ex. B, Mays Report at 24-26. These are conclusions that support Dr. Mays's opinions and also provide notice to Ethicon that Prolene polypropylene undergoes oxidative degradation *in vivo*.

CONCLUSION

For the reasons above, Defendants' Motion to Exclude the Testimony and Opinions of Dr. Jimmy Mays, Ph.D. should be denied in its entirety.

This 9th Day of May, 2016

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CERTIFICATE OF SERVICE

I hereby certify that on May 9th 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive services in this MDL.

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